

REMARKS

Claims 41-43 and 45-58 are pending in the present application, with claims 41 and 58 being the independent claims. By the present Communication, no claims have been added, canceled, or amended. Accordingly, claims 41-43 and 45-58 are currently pending.

Rejection Under 35 U.S.C. §112, First Paragraph

Applicants respectfully traverse the rejection of claims 41-43 and 45-58 under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The Office Action states that the names "ORF" and "heterologous peptide" do not define any structural features and amino acid sequence commonly possessed by the genus, and that the specification does not describe and define any structural features, nucleotide and/or amino acid sequence commonly possessed by the genus. The Office Action concludes that one skilled in the art would not be able to recognize the identity of the claimed genus.

Applicants submit that the presently claimed invention is drawn to nucleic acid expression vectors having defined structural features and molecular architecture. The genus of claimed expression vectors include: 1) a 5'-CACC sequence, 2) a start codon, 3) an open reading frame, and 4) a polynucleotide encoding a heterologous peptide. Within the genus of claimed expression vectors, these features are arranged in a specific, defined architecture. That is, the sequence 5'-CACC is linked immediately 5' to a start codon of an open reading frame (ORF), and the ORF is linked in-frame to a polynucleotide encoding a heterologous peptide. These four features are a part of the standard lexicon of working molecular biologists, and are described in the specification in a manner consistent with their understanding (see e.g., page 4, lines 9-12 (5'-CACC sequence and start codon); page 3, lines 19-25 (open reading frame); page 4, lines 16-17 and page 7, lines 26 through page 8, line 21 (polynucleotide encoding a heterologous peptide)). Thus, in accord with *University of California v. Eli Lilly and Co.*, Applicants' claims and

specification clearly set forth and enable the skilled artisan to identify the common characteristics of the claimed expression vectors.

Applicants' specification also provides thousands of exemplary expression vectors that contain the sequence 5'-CACC linked immediately 5' to a start codon of an open reading frame (ORF), with the ORF in turn linked in-frame to a polynucleotide encoding a heterologous peptide. For example, Example 1 (pages 18-77) provides thousands of examples of expression vectors within the scope of the present claims. These expression vectors contain ORFS that are representative of the entire yeast genome. Example 2 (pages 78-146) provides thousands more examples of expression vectors within the scope of the present claims. These expression vectors contain ORFS that are representative of the entire human genome.

Thus, in accord with *University of California v. Eli Lilly and Co.*, Applicants respectfully submit that the specification as filed fully describes at least one species (tens of thousands of species are in fact disclosed) of the claimed genus such that a skilled artisan can identify other species of the claimed genus.

Accordingly, the specification is fully compliant with the written description requirement of 35 U.S.C. § 112, first paragraph. Applicants respectfully request withdrawal of the rejection.

Rejection Under 35 U.S.C. § 103

Applicants respectfully traverse the rejection of claims 41-43 and 45-58 under 35 U.S.C. §103 as allegedly being unpatentable over Dubensky, in view of Guan and Gregoire.

Establishing prima facie obviousness requires a showing that each claim element is taught or suggested by the prior art. See *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). Absent a showing of such motivation and suggestion, prima facie obviousness is not established. See *In re Fine*, 5 USPQ2d at 1598. A prior art reference must be considered in its entirety, *i.e.* as a whole, including portions that teach away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). The Court of Appeals for the Federal Circuit further instructed that

“references that teach away cannot serve to create a prima facie case of obviousness” (*In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994)), and that an “applicant may rebut a prima facie case of obviousness by showing that the prior art teaches away from the claimed invention in any material respect” (*In re Geisler*, 116 F.3d 1465, 1469 (Fed. Cir. 1997)).

Claims 41-43 and 45-58 are drawn to isolated expression vectors configured such that an “ORF is linked in-frame to a polynucleotide encoding a heterologous peptide, thereby encoding a fusion protein.” Applicants submit that the teachings of the Dubensky reference are directly opposite the presently claimed invention. The Dubensky vectors are configured in a “bicistronic heterologous configuration” specifically designed to prevent the expression of fusion proteins. Dubensky’s bicistronic vectors include a stop codon between each heterologous gene, and are suitable only for the expression of single peptides (see column 90, paragraphs 2 and 3). Accordingly, Dubensky’s bicistronic vectors are specifically designed not to (and cannot) encode fusion proteins as required by the present claims.

In view of the above remarks, the Dubensky reference clearly teaches away from the presently claimed invention. As instructed by The Court of Appeals for the Federal Circuit, the Dubensky reference cannot serve as the basis for a proper §103 rejection. Applicants further submit that neither the Guan nor the Gregoire references may be used to cure this defect.

In view of the foregoing remarks, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a).

In re Application of:

Fernandez et al.

Application No.: 10/003,021

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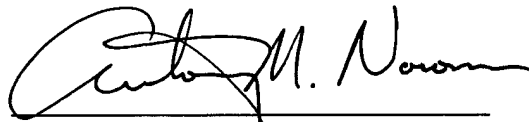
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Conclusion

In summary, for the reasons set forth herein, Applicants maintain that claims 41-43 and 45-58 clearly and patentably define the invention and respectfully request that the Examiner withdraw all rejections and pass the application to allowance. If the Examiner would like to discuss any of the issues raised in the Office Action, the Examiner is encouraged to call the undersigned so that a prompt disposition of this application can be achieved.

Enclosed is Check No. 581545 in the amount of \$1,020.00 for the Three (3) Month Petition for Extension of Time fee. The Commissioner is hereby authorized to charge for any additional required fees, or credit any overpayments to Deposit Account No. 07-1896 referencing the above-identified attorney docket number. A duplicate copy of this Transmittal Sheet is enclosed.

Respectfully submitted,



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